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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,115	07/21/2004	Deborah Philp	4239-64126-13	7111

36218 7590 10/12/2007

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EXAMINER	
TELLER, ROY R	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,115	PHILP ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-23 and 25-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-23 and 25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 7/24/07, in which applicant amended claims 3, 5, 7- 9, 11, 19, 25- 29; cancelled claims 2, 16, 23, 32; and added new claims 34-36.

Claims 1, 3, 5, 7-15, and 17-18 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 19-23 and 25-36 are under examination.

Information Disclosure Statement

The information disclosure statement, received 7/21/04, is acknowledged. A signed copy is enclosed hereto.

Claim Rejections - 35 USC § 112

Claims 19-23 and 25-36 are/stand rejected under 35 USC 112, first paragraph for the reasons of record which are restated below.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the specification provides more than adequate written descriptive

support for the pending claims , including thymosin beta 4 fragments and variants comprising conservative amino acid substitutions. In addition, applicant contends that the specification provides specific examples of thymosin beta 4 fragments and variants. Further applicant contends that the metes and bounds of the claimed thymosin beta 4 polypeptide fragments and variants is clear. However, the examiner contends that one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus or each subgenus. The envisioned fragment or variant of the fragment, in referring to thymosin beta 4 or SEQ ID NO:1 is unclear if only conservative amino acids can be substituted for LKKTET or if conservative variants include no conservative amino acids in certain position so long as the activity of the peptide is retained. Thus one cannot readily ascertain the structural modification necessary to render a thymosin beta 4 or LKKTET variant a conservative variant.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-23 and 25-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed tothe Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the genus of the fragment of thymosin beta 4, which comprises amino acid residues 17-23 (LKKTETQ) or 17-22 (LKKTET) of SEQ ID NO:1, wherein the fragment includes 0 to 5 conservative amino acid substitutions.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species

encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* amino acid residues 17-23 or 17-22 of SEQ ID NO:1. The disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which the fragment of thymosin beta 4, which comprises amino acid residues 17-23 (LKKTETQ) or 17-22 (LKKTET) of SEQ ID NO:1, wherein the fragment includes 0 to 5 conservative amino acid substitutions.

The written description requirement for a claimed genus may be satisfied through sufficient drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features, or critical conserved regions, of the genus and subgenera of proteins to be used in the claimed composition. There is not even identification of

any particular portion of the structure that must be conserved. Structural features that could distinguish the proteins in the genus from others are missing from the disclosure. The specification and claims do not provide any description of what other changes should be made. There is no description of the other sites (other than those which applicant has possession of) at which variability may be tolerated and there is no information regarding the relation of structure to function. The general knowledge and level of those skilled in the art does not supplement the omitted description because specific, not general, guidance is what is needed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed. Thus, no identifying characteristics or properties of the instant polypeptides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus or each subgenus.

The specification does not "clearly allow persons of skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

The metes and bounds of the envisioned fragment or variant of the fragment, in referring to thymosin beta 4 or SEQ ID NO:1 is unclear if only conservative amino acids can be substituted for LKKTET or if conservative variants include no conservative amino acids in certain position so long as the activity of the peptide is retained. Thus one cannot readily

ascertain the structural modification necessary to render a thymosin beta 4 or LKKTET variant a conservative variant.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

Claims 19-31 are/stand rejected under 35 USC 112, second paragraph for the reasons of record which are restated below.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the amended claims clarify the claimed compositions comprise polypeptides which are fragments of thymosin beta 4 or variants of fragments of thymosin beta 4, comprising the recited amino acid residues. However, the examiner contends that this This is vague and indefinite as to the metes and bounds of the envisioned fragment or variant of the fragment, in referring to thymosin beta 4 or SEQ ID NO:1. The claims are indefinite because it is unclear how the envisioned peptide can be both SEQ ID NO:1 and have substitutions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-31 recite a fragment of thymosin beta 4 or a variant of the fragment. This is vague and indefinite as to the metes and bounds of the envisioned fragment or variant of the fragment, in referring to thymosin beta 4 or SEQ ID NO:1. The claims are indefinite because it is unclear how the envisioned peptide can be both SEQ ID NO:1 and have substitutions.

Claim Rejections - 35 USC § 102

Claims 19-23 and 25-36 are/stand rejected under 35 USC 102(b) for the reasons of record which are restated below.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that although the cited prior art reference describes a polypeptide that comprises the sequence LKKTET (thymosin beta 4 amino acid residues 17-22 of instant SEQ ID NO:1) and conservative variants thereof, it does not teach polypeptides of no more than 10 amino acids in length or fragments of thymosin beta 4 polypeptides. In addition the cited prior art does not teach any composition for promoting hair growth in a subject. However, the examiner contends that Kleiman et al. discloses a composition containing a polypeptide comprising the amino acid sequence LKKTET and conservative variants thereof. See, for example, column 11, lines 29-30. Kleiman discloses administering the polypeptide contained in a

topically formulation comprising a hydrogel. See, for example, claim 7. Further, the examiner contends that the instant claims are drawn to a composition , not a method of use (hair growth).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-23 and 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleinman et al. (WO 00/06190).

The instant invention is drawn to a composition comprising a polypeptide of no more than 10 amino acid residues in length comprising an actin-binding peptide, wherein the fragment of thymosin beta 4 comprises amino acid residues 17-23 (LKKTETQ) or 17-22 (LKKTET) of SEQ ID NO:1, wherein the fragment includes 0 to 5 conservative amino acid substitutions, further comprising a pharmaceutically suitable carrier, wherein the pharmaceutically suitable carrier comprises a hydrogel.

Kleiman et al. discloses a composition containing a polypeptide comprising the amino acid sequence LKKTET and conservative variants thereof. See, for example, column 11, lines 29-30. This reads on the limitations of claims 19, 23, and 25-32. Kleiman discloses administering the polypeptide contained in a topically formulation comprising a hydrogel. See, for example, claim 7. This reads on the limitations of claims 20-22.

Therefore, the cited reference is deemed to anticipate the instant claims.

Double Patenting

Claims 19-23 and 25-36 are/stand rejected under nonstatutory obviousness-type double patenting for the reasons of record which are restated below.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that the cited reference does not teach or suggest polypeptides of no more than 10 amino acids in length, nor any fragments of the thymosin beta 4 polypeptide. However, the examiner contends that The '111 application is drawn to a composition comprising a polypeptide comprising the amino acid sequence LKKTET (SEQ ID NO:1) or a conservative variant thereof, the composition further comprising a carrier for application to a surface of the human body.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim19-23 and 25-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-5 and 29 of U.S. PGPUB NO. 2004/0220111. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a composition comprising a polypeptide of no more than 10 amino acid residues in length comprising an actin-binding peptide, wherein the fragment of thymosin beta 4 comprises amino acid residues 17-23 (LKKTETQ) or 17-22 (LKKTET) of SEQ ID NO:1, wherein the fragment includes 0 to 5 conservative amino acid substitutions, further comprising a pharmaceutically suitable carrier.

The '111 application is drawn to a composition comprising a polypeptide comprising the amino acid sequence LKKTET (SEQ ID NO:1) or a conservative variant thereof, the composition further comprising a carrier for application to a surface of the human body. This reads on the limitations of instant claims 19-23 and 25-33.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. PGPUB NO. 2004/0220111, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly

owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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